

<b>Case Number:</b>	CM13-0010647		
<b>Date Assigned:</b>	09/26/2013	<b>Date of Injury:</b>	10/24/2002
<b>Decision Date:</b>	01/23/2014	<b>UR Denial Date:</b>	07/04/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/13/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine & Rehabilitation, has a subspecialty in Interventional Spine, and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The physician reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/She is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 54 year-old female with a 10/24/2002 industrial injury. She has been diagnosed with low back pain with lumbar degenerative disc disease (DDD); cervical DDD; neck and upper back pain; left shoulder degenerative joint disease (DJD); "intrathecal and short-acting"; "end of battery life with pump pocket tenderness"; and, severe constipation. On 6/25/13, ██████████ refilled and reprogramed the intrathecal pump with 20cc Fentanyl 3000mcg per cc, Clonidine 120mcg per cc, and programs it to maintain 1450mcg/day, with a bolus of 75mcg given over 5 minutes. ██████████ states that there is a Court Order to allow the catheter evaluation and a magnetic resonance imaging (MRI) of the catheter tip, which is the standard of care for surveillance of granuloma at the catheter tip. The 7/5/13 ██████████ Utilization Review (UR) letter recommended non-certification for the MRI of the catheter tip, and modified the programming of the pump to allow 15cc fentanyl 3000mcg per cc. UR also denied the use of Flector patches.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**One MRI of catheter tip at lumbothoracic junction to rule out granuloma between 6/25/2013 and 8/31/2013:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation an article: Deer, Timothy R. "A prospective

analysis of intrathecal granuloma in chronic pain patients: A review of the literature and report of a surveillance study." Pain Physician 7.2 (2004); 225-228.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation In this case, the highest ranked standard is likely "Expert Opinion" or "Generally accepted standards of medical practice."

**Decision rationale:** I have reviewed the 7/5/13 UR denial letter from [REDACTED] on the MRI for evaluation of the catheter tip for granuloma. The UR stated they could not find a reference in MTUS/ODG/ACOEM, and stated they used other guidelines. They cited the report from Pain Physician, by T.Deer, "A prospective analysis of intrathecal granuloma in chronic pain patients." UR cited the statement, "Intrathecal granulomas appear to be related to an inflammatory reaction to opioids that cease once the offending drug is discontinued. If imaging is indicated, MRI is the gold standard." The UR denial suggests discontinuing the offending opioid, and speculated that this would stop or resolve the granulation tissue and make the MRI unnecessary. On reviewing other guidelines, there is no evidence-based guideline that specifically states an MRI is not indicated to evaluate a catheter tip granuloma. The Pain Physician article cited by the UR identifies "MRI is the gold standard" and this appears to be consistent with the standard of care and expert opinion by [REDACTED]. Therefore, I am recommending approval.

**One refill/reprogramming of pump with 20cc Fentanyl 3000mcg per cc & Clonidine 120mcg per cc between 6/25/2013 and 8/31/2013:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Section Pain (Chronic): Clonidine, Intrathecal

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Intrathecal Drug Delivery Systems, Medications Page(s): 54-55.

**Decision rationale:** The employee has been having pain relief and improved function with the intrathecal pump with fentanyl. Unfortunately, the definition of medical necessity has changed with SB863, and the addition of LC4610.5(2) basically means that treatment is solely based on MTUS guidelines. In this case, MTUS for intrathecal drug delivery systems specifically states "Other opioids (including Fentanyl and Sufentanil) have been used for intrathecal chronic non-malignant pain, but are non-FDA approved and have little research associated with their use." The MTUS guidelines do not recommend non-FDA approved products. The non-FDA-approved use of fentanyl in the intrathecal pump is not in accordance with MTUS guidelines. Therefore, I am recommending denial.

**One prescription of Flector patch #60 with 2 refills between 6/25/2013 and 9/30/2013:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Flector (r) patch. Decision based on Non-MTUS Citation Official disability Guidelines (ODG), Section Pain (Chronic)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** The employee is diagnosed with neck, back, and shoulder pain. For topical NSAIDs, MTUS guidelines specifically indicate: "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. " The use of Flector Patches on the employee's neck, spine or shoulder is not in accordance with MTUS guidelines. Therefore, I am recommending denial.